PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Randy L. Morningstar	**Examiner:**	ODLAND
Serial No.:	09/872,704	**Group Art Unit:**	3743
Filed:	June 1, 2001		
For:	IMPLANTABLE MEDICAL BALLOON AND METHOD OF MAKING	**Docket No.**	687-442

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Linda K. Newton

APPEAL BRIEF

The Applicant filed a Notice of Appeal on February 18, 2004 from the final rejection of the Examiner dated November 18, 2003.

This Appeal is proper because the present application includes claims that have been finally rejected. Applicant's Brief in support of this Appeal follows.

REAL PARTY IN INTEREST

The real party in interest in this Appeal is AMS Research Corporation, a wholly owned subsidiary of American Medical Systems, the assignee of all rights to the invention disclosed in the subject application. An assignment of the inventors' rights to American Medical Systems was recorded in the United States Patent and Trademark Office on September 27, 2001, at Reel 012008, Frame 0811.

RELATED APPEALS AND INTERFERENCES

There are no known appeals or interferences related to this Appeal.

STATUS OF THE CLAIMS

The present application was originally filed with claims 1-80. In an Office action dated September 24, 2003, the Examiner required restriction between claims 1-19 and 52-61 (Group 1(A)), claims 62-66 (Group 1(B)), claims 20-51 (Group II(A)), claim 67 (Group II(B)) and claims 68-88 (Group III(C)). In a Response dated October 9, 2002 and in a subsequent telephone conversation, Applicant elected to prosecute Group 1(A).

In a non-final Office Action dated December 4, 2002, the Examiner withdrew claims 20-51 and 62-88 from further consideration as being drawn to a non-elected invention. The Examiner also objected to the drawings and the specification as requiring minor corrections. Additionally, claims 1-19 and 52-61 were rejected as being obvious under 35 U.S.C. §103(a) in view of several references. In a Response dated March 4, 2003, Applicant corrected the drawings and specification and amended claim 11 as presented in the Appendix. Applicant also argued that the claims were patentable over the cited references, and requested withdrawal of the rejection.

In a second non-final Office Action dated April 3, 2003, the Examiner withdrew the previous rejections, but rejected claims 1-19 and 52-61 as being anticipated by and/or obvious in view of newly cited prior art. In a Response dated July 3, 2003, Applicant argued

that the claimed invention was patentable over the cited references, and requested withdrawal of the rejection.

In a third non-final Office Action dated July 24, 2003, the Examiner withdrew the previous rejections, but rejected claims 1-19 and 52-61 as being anticipated by and/or obvious in light of newly cited prior art. In a response dated October 9, 2003, Applicant argued that the claims were patentable over the cited references, and requested withdrawal of the rejections.

In a Final Office Action dated November 18, 2003, the Examiner held the Applicant's previously submitted arguments unpersuasive and reasserted the rejection of claims 1-19 and 52-61. In a Response After Final Rejection dated February 17, 2004, Applicant reasserted that the claims were patentable over the cited references. Applicant also filed a Notice of Appeal dated February 18, 2004. In an Advisory Action dated March 3, 2004, the Examiner stated that the Applicant's Response After Final Rejection was not entered because it did not put the application in condition for allowance.

Accordingly, claims 1-19 and 52-61 are the subject of this Appeal. A copy of the pending claims is set forth in the Appendix attached hereto.

STATUS OF AMENDMENTS

No claim amendments have been presented after final rejection, with the exception of a Draft Amendment After Final dated February 12, 2004 that was not formally submitted or entered. All prior claim amendments have been entered by the Examiner. The claims listed in the Appendix reflect all amendments presented in the course of prosecution.

SUMMARY OF THE INVENTION

The present invention is generally directed to a medical balloon that is implantable in human tissue. (Abstract). In a preferred embodiment, the balloon includes a self-sealing valve portion that is coated in silicone to form a balloon wall around, and integral with, the valve portion. (Abstract). One or more balloons may be implanted to treat, for example, urinary incontinence or vesicoureteral reflux. (Abstract).

Fig. 1 illustrates the device 10 of the present invention in an inflated state. The device 10 includes a valve portion 20 and a balloon portion 70. Referring to Fig. 2, the valve portion 20 includes a valve body 22 defining an inlet 22 and a stem 26. When the valve portion is attached to the balloon portion, the valve stem can extend into an inner chamber 72 of the balloon portion 70. (Par. [0022]).

The valve portion 70 may be formed from an elastomeric material such as silicone that may be pierced by a piercing implement, and remain fluid-tight after the piercing implement is removed (par. [0023]). In this manner, a piercing 32 is defined by the valve portion 20 to provide a path for an inflation tube to follow when inserted into the device 10 (par. [0023]). In one embodiment, the piercing begins in inlet 24 along longitudinal axis 34 until it reaches a predetermined location in the valve stem 26 where a curved portion or bend 36 is formed in the piercing 32 such that the piercing 32 exits the side 28 of valve stem 26. (Par. [0023]).

The device 10 may be prepared by repeatedly dipping a pre-formed valve portion 20 into a silicone dispersion until a meniscus plug 76 (Fig. 4B) is formed. (Par. [0036]). The device 10 is then subjected to a series of vulcanization and evaporation steps. (Pars. [0037]-[0041]). Finally, the piercing is formed using a sharp instrument.

ISSUES ON APPEAL

Claims 1-9, 11-13 and 16 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,327,912 to Hoffman. ("Hoffman").

Claims 10, 14-15, 17-19 and 52-61 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hoffman in view of U.S. Patent No. 5,720,734 to Copenhaver et al. ("Copenhaver").

In view of these rejections, the issues on appeal are:

A. Whether claims 1-9, 11-13 and 16 are patentable over Hoffman under 35 U.S.C. § 102(b);

B. Whether claims 10, 14-15, 17-19 and 52-61 are patentable over Hoffman in view of Copenhaver under 35 U.S.C. § 103(a).

GROUPING OF CLAIMS

Applicants contend, for the purposes of this Appeal only and without prejudice to Applicants' rights, that the appealed claims fall into the following groups:

For the rejection over Hoffman: claims 1-9, 11-13 and 16 stand or fall as a group.

For the rejection over Hoffman in view of Copenhaver: claims 10, 14-15, 17-19, and 52-61 stand or fall as a group.

ARGUMENT

A. Claims 1-9, 11-13 AND 16 ARE PATENTABLE OVER HOFFMAN.

Claims 1-9, 11-13 and 16 were rejected under 35 U.S.C. § 102(b) as being unpatentable over Hoffman.

Claim 1 generally recites an implantable balloon including a valve body defining an inlet, a valve stem extending from the body opposite the inlet and a piercing extending from the inlet. The piercing remains closed and fluid-tight unless penetrated by a relatively rigid member.

Hoffman reports an improved tennis ball having a valve integrally molded into the sidewall of the ball. (Abstract). The valve is formed from a tapered deformable elastomeric material such that in a closed position, the ball is sealed by and against internal pressures. (Abstract). However, the ball can be placed in a pressurized environment such as a pressurized container to increase the internal pressure of the ball.

It is well established that for a reference to anticipate a claim under § 102, every claim limitation must be expressly or inherently taught by the reference. Applicant respectfully submits that Hoffman fails to teach several limitations of each of the rejected independent claims.

1. Hoffman Does Not Teach Or Suggest Having A Piercing Configured To Remain Closed Unless Penetrated By A Relatively Rigid Member.

Independent claims 1 and 11 each recite a valve member including a piercing that remains closed unless penetrated by a relatively rigid member (claim 1) or unless a substantially rigid member is pushed through the piercing (claim 2).

Conversely, Hoffman reports a valve "which has no exposed opening through which to apply a fixed pressure source..." (Col. 8, lines 3-5). For this reason, the ball reported in Hoffman must be placed in a pressurized storage container to be fully inflated. (Col. 8, lines 6-20). Thus, Hoffman fails to report or suggest at least two features of the claimed invention. First, the valve reported in Hoffman cannot be pierced by a relatively rigid member as recited in claims 1 and 11 because no opening exists to access the valve. Furthermore, the valve reported in Hoffman does not remain closed unless penetrated by a rigid member because the valve must open when placed in a pressurized container in order to properly pressurize the ball. Applicant respectfully requests reversal of this rejection.

2. Hoffman Does Not Teach Or Suggest An Implantable Balloon.

The preamble of independent claim 1, recites the term "implantable." The preamble of claim 11 a "medical balloon" that is "implantable in a human body." Applicant respectfully submits that the tennis ball reported in Hoffman is not implantable.

There is no litmus test with respect to whether the words in a preamble merely constitute a statement of purpose rather than additional structural limitations that further define the claimed invention. *Corning Glass Works v. Sumitomo Electric U.S.A.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989). Generally speaking, when a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use, the preamble does not constitute a claim limitation. *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997). However, where a patentee uses the claim preamble to recite structural limitations of the claimed invention, courts should give effect to the preamble's usage. *Id.* The effect given to the preamble should be based on a review of the entire application to gain an understanding of what the inventor actually invented and intended to encompass by the claims. *Id.*

In *Corning Glass*, the claim at issue recited "an optical waveguide" in the preamble, as well as two structural limitations in the claim body. *Corning glass*, 868 F.2d at 1256. The prior art disclosed an optical fiber having the limitations in the claim body, but the optical fiber did not function as an optical waveguide. *Id.* After reviewing the specification of the patent at issue, the CAFC determined that an optical waveguide is a unique type of optical fiber, and thus, the claim was not only limited to optical fibers having the structural limitations in the body of the claim, but was further limited to optical fibers having the structural limitations that could function as optical waveguides. *Id.* at 1256-57. Thus, the

court held that the claimed invention was not anticipated by the prior art reference because the preamble included an additional limitation that defined over the prior art.

In *Rowe*, the claim at issue recited a balloon angioplasty catheter in the preamble, while the relevant prior art reference disclosed a general purpose catheter. *Rowe*, 112 F.3d at 476. After analyzing the specification, the CAFC determined that the phrase "balloon angioplasty catheter" recited in the preamble had a specific meaning that distinguished it over a general purpose catheter. *Id.* at 479-80. Thus, the CAFC held that the claimed invention defined over the prior art because of the limitation recited in the preamble.

The foregoing cases indicate that the language of a preamble constitutes a claim limitation when the specification indicates that the inventor(s) intended to limit their invention to that described in the preamble. In contrast, the preamble does not constitute a claim limitation when the language merely recites an intended use of the invention.

Applicant respectfully submits that even a cursory review of the specification demonstrates that the preambles of claims 1 and 11 recite limitations that distinguish the claimed invention over the tennis ball of Hoffman.

Beginning with the title ("An *Implantable* Medical Balloon and Method of Making") and carrying through the Abstract, Applicant defined and limited the claimed invention to a device sized and configured for implantation in a patient. For example, the Background reports that implantable microballoons provide a minimally invasive treatment for urinary incontinence and other medical procedures. (Par. [0003]). The Background further notes that previous microballoons presented performance and manufacturing problems due to the small size of the microballoons and the complexity of the valves used in the microballoons. (Par.

[0005]). Likewise, the Abstract refers to the invention as a medical balloon, *implantable* in human tissue, for treating urinary incontinence, vesicoureteral reflux and/or embolization of blood vessels.

The foregoing demonstrates that the inventors were working on a particular problem in the field of implantable microballoons, and not in the field of balloon valves generally. See *Corning Glass*, 868 F.2d at 1257 ("the inventors were working on the particular problem of an effective optical communications system not on general improvements in conventional optical fibers."). Thus, claims 1 and 11 should be interpreted as being limited to devices that are implantable in human tissue. Applicant respectfully requests reversal of this rejection.

B. Claims 10, 14-15, 17-19 And 52-61 Are Patentable Over Hoffman In View of Copenhaver.

Claims 10, 14-15, 17-19 and 52-61 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hoffman in view of Copenhaver. Copenhaver generally reports a valve for use in a gastrostomy port that prevents leakage of bodily fluids out of a stoma. The Examiner stated that although Hoffman does not teach every claim limitation recited in the rejected claims, Copenhaver teaches the limitations not taught by Hoffman, and that it would have been obvious to modify Hoffman as taught by Copenhaver.

It is well established that a person of ordinary skill in the art must be motivated to select and/or combine prior art references to render a claim obvious.

1. Both Hoffman And Copenhaver Constitute Non-Analogous Prior Art.

To rely on a reference as a basis for rejecting an applicant's invention, the reference must be either in the field of the applicant's endeavor or reasonably pertinent to the particular problem with which the inventor was concerned. *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1997). With this in mind, it is necessary to look at the reality of the circumstances – in other words, common sense – in deciding which fields a person of ordinary skill would look to for a solution to a problem facing the inventor. *Id.*

The claimed valve addresses two primary problems. First, the valve must be sized and configured for in vivo implantation and inflation using an inflating tube. Second, the valve must be configured to prevent fluid leakage such that the balloon remains pressurized. Applicant respectfully submits that a person of skill in the art would not look to prior art directed to valves used in a tennis ball to solve these problems.

There is no question that the tennis ball valve reported in Hoffman is not in the field of the Applicant's endeavor (i.e. implantable devices). Likewise, the problem solved by the valve reported in Hoffman is not relevant to the problems with which the present invention is concerned. First, there are clear structural and size differences between a microballoon and a tennis ball. Second, the respective devices are being used in an entirely different environment, and are subjected to different rigors in that environment. Third, as previously noted, the valve reported in Hoffman is not inflatable using a needle or similar device. Fourth, the reliability requirements of a medical implant are completely different than those of a tennis ball. Therefore, a person of ordinary skill in the art would not look to Hoffman for solutions to the problems addressed by the claimed invention.

Copenhaver is likewise non-analogous. Although the invention reported in Copenhaver is generally directed to a valve used in a medical device, the primary purpose of valve reported in Copenhaver is to allow for repeated injections of medicine, etc., into a patient through a stoma port without allowing reflux of gastric fluids. The valve reported in Copenhaver does not address the problem of preventing leakage of pressurized systems as addressed by the claimed invention because the Copenhaver valve is not associated with a pressurized system such as a balloon. Furthermore, Copenhaver does not address the problem of in vivo inflation of the implantable balloon. Applicant requests reversal of this rejection.

2. There Is No Motivation To Modify Hoffman With Copenhaver.

It is well established that the prior art must provide some suggestion or motivation in the art to combine and/or modify prior art references to render a claimed invention obvious. Applicant respectfully submits that there is no motivation to modify Hoffman based on Copenhaver.

In addition to the vastly different environments under which each of these reported valves operate, and the entirely different use of these valves, Hoffman reports a valve for a pressurized system that cannot be inflated with a needle or other fixed source of pressure. Conversely, Copenhaver reports a valve for use in an unpressurized gastrostomy port that must be able to withstand repeated injections without leaking. Applicant respectfully submits that Hoffman and Copenhaver teach away from one another because Hoffman reports a valve that cannot be accessed by a needle, while Copenhaver reports a valve in

which repeated injections are an essential feature of the valve. Therefore, a person of skill in the art would not be motivated to modify Hoffman with Copenhaver.

3. The Combination of Hoffman and Copenhaver Does not Teach or Suggest Every Limitation of the Claimed invention.

Even if a person of skill in the art were motivated to modify Hoffman as taught by Copenhaver, the combination of these references does not teach or suggest every limitation of the rejected claims.

The preamble of claims 1 and 11 (upon which claims 10, 14-15 and 17-19 depend) and claim 52 recite that the claimed balloon is implantable in the preamble. As previously discussed, and reiterated for the purpose of the present rejection, Hoffman does not report or suggest this feature. Likewise, Copenhaver, which is generally directed to an anti-reflux valve, does not report or suggest an implantable balloon. Therefore, every claim limitation is not taught or suggested by the cited references, and Applicant respectfully requests reversal of this rejection.

CONCLUSION

The references cited in the Final Rejection fail to teach or suggest limitations recited in the rejected claims. Furthermore, with regard to the obviousness rejection, the cited references constitute non-analogous prior art that are not properly combinable.

Accordingly, pending claims 1-19 and 52-61 are allowable over the prior art of record. Applicants respectfully requests that the Board reverse the outstanding rejection of the pending claims, and that the application be returned to the Examiner for processing in accordance with that reversal.

Please charge the appropriate fee of $320.00 for the filing and consideration of this Appeal Brief to our Deposit Account No. 501921. Should any additional fee be required, the Commissioner is authorized to charge our Deposit Account No. 501921 and is requested to notify us of the same.

Respectfully Submitted,

RANDY L. MORNINGSTAR

By: _____

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Dated: April 12, 2003

M2:20613584.01

APPENDIX

PENDING CLAIMS

1. (Original) An implantable balloon comprising:

a valve portion having:

a valve body defining an inlet;

a valve stem extending from said body opposite said inlet;

a piercing extending from said inlet, through said body and stem, said valve portion constructed from a soft, elastomeric material having memory thereby causing said piercing to remain closed and fluid-tight unless penetrated by a relatively rigid member;

a balloon portion, integral with said valve portion, constructed and arranged to receive and hold fluids exiting said piercing opposite said inlet

2. (Original) The balloon of claim 1 wherein said valve stem comprises at least one side.

3. (Original) The balloon of claim 1 wherein said valve stem comprises a rounded tip.

4. (Original) The balloon of claim 1 wherein said valve stem comprises a side and said valve portion further has a sidewall, laterally displaced from said valve stem side, and integral with an inside surface of said balloon portion.

5. (Original) The balloon of claim 1 wherein said valve portion is substantially cylindrical.

6. (Original) The balloon of claim 1 wherein said valve body, said valve stem, and said inlet are substantially cylindrical and substantially concentric.

7. (Original) The balloon of claim 1 wherein said valve stem comprises at least one side and said piercing extends through said side of said stem.

8. (Original) The balloon of claim 1 wherein said valve stem comprises a side and said valve portion further has a sidewall extending from said valve body, laterally displaced from said valve stem side.

9. (Original) The balloon of claim 8 wherein said valve body forms a curved web, integrally connecting said valve portion sidewall with said valve stem side, said curved web being concave and opening toward said balloon portion.

10. (Original) The balloon of claim 1 wherein said soft, elastomeric material comprises silicone.

11. (Previously Presented) A self-sealing medical balloon of unitary construction, implantable in a human body, comprising:

a cylindrical valve body having a predetermined diameter and an upper side and

a lower side;

an inlet defined by said valve body lower side;

a cylindrical valve stem extending upwardly from said valve body, said valve stem having a diameter smaller than said valve body diameter;

a balloon wall adapted to receive and hold fluids, the balloon wall extending upwardly from said valve body, said balloon wall having an inner diameter, while in a deflated state, which is larger than said valve stem diameter such that an annular space exists between said balloon wall and said valve stem while said balloon is deflated, said annular space provided to relieve stress from a union of said balloon wall and said valve body when said balloon is inflated;

a piercing extending from said inlet, through said valve body and through said valve stem, into an inner chamber defined by said balloon, said piercing constructed and arranged to remain closed unless a substantially rigid member is pushed through said piercing, such as to inflate said balloon, whereby said piercing member recloses after said member is withdrawn, thereby preventing a fluid from escaping from said inner chamber.

12. (Original) The balloon of claim 11 whereby said inlet, said valve body, and said valve are substantially concentric, sharing a common longitudinal axis.

13. (Original) The balloon of claim 12 whereby said piercing follows said longitudinal axis.

14. (Original) The balloon of claim 12 whereby said piercing comprises a curved portion.

15. (Original) The balloon of claim 12 whereby said piercing comprises a straight portion and a curved portion, said straight portion extending upwardly from said inlet and substantially parallel to said axis, said curved portion extending from said straight portion to a side of said valve stem.

16. (Original) The balloon of claim 11 wherein said annular space is defined on a lower side by a curved web which is concave and opening upwardly.

17. (Original) The balloon of claim 11 wherein said balloon is constructed entirely of silicone.

18. (Original) The balloon of claim 11 further comprising a removable skirt extending downwardly from said valve body, said skirt providing a surface which may be handled during a balloon manufacturing operation without damaging said balloon wall, or said valve body.

19. (Original) The balloon of claim 18 wherein said removable skirt has an outside diameter smaller than an outside diameter of said valve body such that a ridge is formed between said valve body and said skirt.

52. (Original) Implantable balloon operably attached to the valve, the valve comprising:

a substantially cylindrical body defining an inlet, concentric with said body, opening in a direction opposite the balloon;

a valve stem, integral with said body, having a substantially cylindrical side and rounded tip opposite said body and leading to an interior of the balloon;

a piercing, defined by said valve body and said valve stem, extending from said inlet toward said balloon and leading to the interior of the balloon, said piercing having a bend which curves toward said stem side;

a cylindrical sidewall, integral with said body, extending in a direction toward said
balloon, radially displaced from said stem side, thereby creating an annular space between said stem and said sidewall, said sidewall having an external surface attachable to said balloon.

53. (Original) The valve of claim 52 wherein said body further defines a curved portion, concave so as to open toward said balloon interior, connecting said sidewall with said stem.

54. (Original) The valve of claim 52 further comprising an end portion, integral with and extending from said sidewall, which curves inwardly to define an opening having an inner diameter which is smaller than an inner diameter of said cylindrical sidewall.

55. (Original) The valve of claim 52 wherein said cylindrical wall comprises a lower sidewall and an upper sidewall and a taper connecting said lower sidewall and said upper sidewall, whereby said lower sidewall has a larger outside diameter than an outside diameter of said upper sidewall.

56. (Original) The valve of claim 55 wherein said upper sidewall and said lower sidewall have substantially equal inner diameters.

57. (Original) The valve of claim 52 further comprising a skirt extending from said body in a direction opposite said balloon.

58. (Original) The valve of claim 57 wherein said skirt has an outer diameter smaller than an outer diameter of said valve body, thereby providing a visual and tactile

definition of an extent of said skirt, such that said skirt may be removed without removing material from said valve body.

59. (Original) The valve of claim 57 wherein said skirt is sized to frictionally fit within an open end of a dipping tube.

60. (Original) The valve of claim 52 wherein said valve is unitarily constructed from an elastomeric material.

61. (Original) The valve of claim 60 wherein said valve is unitarily constructed from silicone.

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Patent
Docket No: 687-442

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Group Art Unit: 3743

Serial No.: 09/872,704
Filed: June 1, 2001 Examiner: Odland
For: Implantable Medical Balloon and Method of Making

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, Alexandria, VA 22313-1450 on:

April 12, 2004 Linda K. Newton
Date Signature: Linda K. Newton

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Alexandria, VA 22313-1450

Commissioner:

Enclosed please find an Appeal Brief in triplicate.

Please charge the fee under 37 CFR, Section 1.17(c) to our Deposit Account No. 501921.

Respectfully submitted,

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Enclosures

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DUPLICATE

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